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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,937	02/20/2002	Masahiro Nomura	219277US0PCT	2562

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EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/31/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/049,937

Applicant(s)

NOMURA ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15 and 25-30 is/are rejected.
- 7) ☒ Claim(s) 16-24 and 31-36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This is a response to Applicant's remarks filed 1-16-03. Claims 13-36 are pending in this application.

The rejection under 35 U.S.C. 103 has been maintained.

The rejection under 35 U.S.C. 112 second paragraph from the Office Action mailed 8-23-02 has been overcome with Applicant's amendments.

The claim objections from the Office Action mailed 8-23-02 have been overcome with Applicant's amendments.

Please note that throughout this Office Action the EP 0846693 reference will be referred to (not the 08333355 reference).

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15, and 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0846693, Maeda et al..

Applicant claims substituted benzylthiazolidine-2,4-dione derivatives for use in reducing blood glucose and in treating metabolic diseases such as hyperlipidemia. Maeda et al. teach N-benzylthiazolidylbenzamide derivatives which are useful in blood sugar-lowering drugs and in treating hyperlipidemia. See page 2, lines 6 and 20-21 for the methods of use. Maeda et al. generically teach the instant compounds on page 2, lines 30-46. Maeda et al. teach species examples of the instant compounds on

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page 13, examples 17-21. Maeda et al. teach the instant compounds, when in the instant compounds, R1 denotes 3-trifluoromethyl and R2 denotes hydrogen.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-15, and 25-30 are rejected under 35 U.S.C. 103(a) as being anticipated by EP 0846693, Maeda et al..

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicant claims substituted benzylthiazolidine-2,4-dione derivatives for use in reducing blood glucose and in treating metabolic diseases such as hyperlipidemia. Maeda et al. teach N-benzylidioxothiazolidylbenzamide derivatives which are useful in blood sugar-lowering drugs and in treating hyperlipidemia. See page 2, lines 6 and 20-21 for the methods of use. Maeda et al. generically teach the instant compounds on page 2, lines 30-46. Maeda et al. teach examples which are similar to the instant compounds in page 14, examples 29, 32 and 33, and page 16, example 46. Maeda et al. teach examples which are similar to the instant compounds, when in the instant compounds, R1 denotes 3-trifluoromethyl and R2 denotes hydrogen. Maeda et al. teach species examples of the instant claims in page 13, examples 17-21. Maeda et al. teach species examples of the instant compounds when, in the instant compounds, R1 denotes 3-trifluoromethyl and R2 denotes hydrogen.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

A difference between Maeda et al. and the instant claims is that Maeda et al. teach a broader genus than the instant claims. An additional difference is that Maeda et al. teach a homolog of the instant compound in example 33 wherein R3 is EtO. In the instant claims the corresponding group is MeO.

Maeda et al. teach positional isomers of the instant claims in examples 29 and 32, wherein R3 is in the 4-position and the 2-position respectively. In the instant claims, the corresponding group is in the 6-position.

*Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)*

Regarding the positional isomers taught by Maeda et al., nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by Maeda et al., since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950). One of ordinary skill in the art would be motivated to use the teachings of Maeda et al. to prepare the instant compounds in the expectation that positional isomers would be useful in treating hyperlipidemia. Further motivation is provided because Maeda et al. teaches specific examples of the instant compounds (supra).

Regarding the homolog taught by Maeda et al., to those skilled in chemical art, one homolog is not such an advance over an adjacent member of a series because chemists knowing properties of one member of a series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious because one skilled in the art would have been

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motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used in treating hyperlipidemia. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

### ***Claim Objections***

Claims 16-24 and 31-36 are objected to because of the following informalities: Claims 16-24, and 31-36 are objected to as being dependent upon a rejected base claim. Appropriate correction is required.

### ***Response to Arguments***

Applicant's arguments filed 1-16-03 have been fully considered but they are not persuasive. Applicant argues that the data shown in the Table strikingly demonstrates that claimed compounds are about 3 times more active for PPAR $\gamma$  as compared to Example 14 of Maeda '693. However, Example 14 is only one compound taught by Maeda et al. Applicant has not shown that the instantly claimed compounds have unexpected results when compared to Examples 17-21, 29, 32, 33, and 46 of Maeda et al. . Therefore, the rejection of the instant compounds over Maeda et al. is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



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DEBORAH C. LAMSKIN  
PRIMARY EXAMINER

*Deborah C. Lamskin for*  
\_\_\_\_\_  
Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

March 26, 2003